DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION
9/2914

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

May 30, 2001

WARNING LETTER
2001-DT-18

Art Birk
Chairman of the Board
Indiana Lions Eye Bank, Inc.
702 Rotary Circle
Indianapolis, Indiana 46202

Dear Mr. Birk:

The Food and Drug Administration (FDA) conducted an inspection of your tissue bank at the above address from March 26, 2001 through April 3, 2001. During this inspection, our investigator documented significant violations of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations, Part 1270 (21 CFR 1270), as follows:

1) Failure to follow your written procedures for designating and identifying quarantined tissue, as required by 21 CFR 1270.31(c). For example: Although your written procedures require that the medical director designate and authorize, in writing, the responsible individuals who have been trained and qualified to conduct and document donor suitability reviews, the employees currently performing these duties have not be authorized by the medical director to perform this work.

2) Failure to quarantine human tissues until donor screening has been completed, reviewed by a responsible person, and determined to assure freedom from risk factors for and clinical evidence of HIV infection, hepatitis B, and hepatitis C, as required by 21 CFR 1270.33(b)(2), in that:

   A) Corneas from the following donors were released from quarantine despite lacking adequate information to assure freedom from risk factors for and/or clinical evidence of HIV infection, hepatitis B, and/or hepatitis C: Donor [redacted], donor [redacted] and donor [redacted], donor [redacted] donor [redacted].

   B) Corneas from the following donor were released from quarantine despite the Medical and Social History Questionnaire for donor [redacted] lacking the interviewer's name, signature and the date and time of its completion.

3) Failure to maintain accurate records which identify the person performing the work, the dates of the various entries, and providing a complete history of the work performed as the records relate to the particular tissues involved, as required by 21 CFR 2170.33(a). For example:

A) The Medical and Social History Questionnaire for donor [redacted] lacking the interviewer's name, signature and the date and time of its completion.

B) The employee purportedly witnessing the consent for donation for donor [redacted] did not sign the consent form as a witness.

C) The recovery lot record for donor [redacted] was not signed and dated by the person performing the work.

4) Failure to have written procedures for all significant steps in infectious disease testing, as required by 21 CFR 1270. 31(a). For example, the procedures for the recovery of amnion tissue do not specify the viral marker testing to be performed on the donor and there are no instructions directing what type of tube(s) to use for donor blood sample collection.

5) Failure to have the written procedures for performing all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor readily available to personnel who may perform the procedures, as required by 21 CFR 1270.31(b). For example:

A) Your written procedures manual [see Standard Operating Procedure (SOP) 10-04023] references SOP 10-02005, [redacted] but this SOP is not listed in the index of procedures and could not be found in your written procedures.

B) Your written procedures manual for Multi-Tissue does not contain the most recent revision of SOP 10-02001, [redacted]

During the inspection, the investigator verbally noted several objectionable observations. Specifically, the investigator noted that you have failed to follow proper procedures concerning the maintenance and calibration of your specular microscope, in that calibration was not performed annually as prescribed in SOP 3200, [redacted] Calibration of the specular microscope was last performed in July 1999. Additionally, it was noted that your revised procedure [SOP AM.01.002, revision 1, [redacted] effective date February 23, 2001] no longer requires the operation of the laminar flow hood for at least

[redacted] minutes prior to use. We note that you have not provided any data to ensure that the removal of this step from your procedures will not increase the likelihood of contamination and/or cross-contamination by infectious disease agents during processing of amnion tissue.

A copy of the List of Inspectional Observations (Form FDA 483) issued at the conclusion of the inspection is enclosed for your information and reference.

This letter is not intended to be an all-inclusive list of the deficiencies that may exist at your facility. It is your responsibility to ensure that your tissue bank is in compliance with all applicable federal regulations.

We have reviewed your April 11, 2001 response to the List of Observations, Form FDA-483, issued at the conclusion of the inspection and conclude that your response is inadequate, as follows:

1. No documentation has been provided to support the statement, in response to FDA 483 observation 2b, that: "...we confirmed the rule out of hepatosplenomegaly was documented during the donor's physical examination...".

2. The response to FDA 483 observation 2C states that the donor's perianal and genitalia revealed no indications of high-risk behavior. Your firm appears to have examined these areas for the signs and symptoms of high-risk behavior. However, other signs and symptoms regarding high-risk behavior were not assessed. For example: blue or purple spots consistent with Kaposi's sarcoma and needle tracks, including examination of tattoos, was not assessed since an examination of the donor's dorsal area was not performed because of the donor's size.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. Some of the available enforcement actions are an Order for Retention, Recall and/or Destruction and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to Sandra Williams, Compliance Officer, at the above address.

Sincerely,

David M. Kaszubski
Acting District Director
Detroit District

Enclosure: FDA 483

CC via certified mail w/enclosure: [redacted]

CC via certified mail w/enclosure: [redacted]

CC via certified mail w/enclosure: [redacted]